

## Annex 1 – Minimal requirements

Tenderer has to take note of these minimal requirements, sign this document and submit it with his tender.

| Subject 1A: Functional requirements |                                                                                                                                                                                                                                                                                          |
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| 1.1                                 | The QA-tool must offer the user the possibility to visually monitor assay stability and laboratory performance                                                                                                                                                                           |
| 1.2                                 | The QA-tool must be able to integrate data from multiple BD-COR systems from three separate laboratory sites                                                                                                                                                                             |
| 1.3                                 | For analyzing and reporting purposes the QA-tool must be able to run analyses and generate reports on the site of the laboratories, using the data of that site, whether or not plotted/benchmarked in comparison with the total data of all sites,                                      |
| 1.4                                 | For analyzing and reporting purposes the QA-tool must be able to run analyses and generate reports for BVO-NL, using the data of all participating laboratories                                                                                                                          |
| 1.5                                 | The interface of the QA-tool must be user-friendly and intuitive                                                                                                                                                                                                                         |
| 1.6                                 | The QA Tool must be able to process results into predefined intra and inter-laboratory comparison graphs on a periodic basis.                                                                                                                                                            |
| 1.7                                 | The QA Tool must be able to process results into intra and inter-laboratory comparison (predefined) graphs on (ad-hoc) request, thereby using all data available at that time (data update from BD to the secure database and the QA tool with a maximum delay of one overnight period). |
| 1.8                                 | The QA Tool data storage location should be able to receive raw data files on an overnight basis, in such a way that files are available for QA purposes at the start of the first working day after the completion of the HPV run on the BD Cor system (see Annex A).                   |
| 1.9                                 | The QA Tool must provide an automatic alert system (e.g., based on Westgard rules) for deviations based on calculations on the dataset with or without pre-defined acceptance criteria.                                                                                                  |
| 1.10                                | The QA Tool must be able to process results into (pre-defined) trend analysis graphs.                                                                                                                                                                                                    |
| 1.11                                | It is required that the limit values, if required by e.g. changes of batches of critical reagents, can be changed. It is thereby essential that the limit values belonging to the previous period will be maintained.                                                                    |
| 1.12                                | The QA Tool must be able to perform calculations on an extracted dataset.                                                                                                                                                                                                                |
| 1.13                                | The QA Tool must be able to present and display results in a tabulated and graphical format using standardized dashboard functionality.                                                                                                                                                  |
| 1.14                                | The QA Tool must provide a data mining tool to easily get more insight in the effect of specific data parameters on the quality of performance of the HPV assay by user defined (ad hoc) queries.                                                                                        |
| 1.15                                | The QA Tool must have a hover functionality in which underlying information on relevant parameters is shown per datapoint in the graphical presentation of results.                                                                                                                      |
| 1.16                                | The QA Tool must be able to generate periodic and ad hoc queries and reports based on specific selection criteria.                                                                                                                                                                       |
| 1.17                                | The QA Tool must provide a display and export function for results to enable external (extended) data analysis (role/right based).                                                                                                                                                       |
| 1.18                                | The QA Tool contains a functionality to export results presented in tables, figures and results from ad hoc queries. (at least xls, doc, jpeg and pdf format)                                                                                                                            |

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| 1.19 | The QA Tool must support dedicated (standardized) analyses on a subset of the laboratories data, e.g., using the results from control samples (V&V panels and UDEC) (to be selected based on sample IDs).      |
| 1.20 | BVO NL will be involved in the design of the output and acceptance of the QA-tool configuration.                                                                                                               |
| 1.21 | The QA Tool must be able to process results into machine errors graphs to visualize user and system failures.                                                                                                  |
| 1.22 | It must be possible to implement changes in the QA Tool as becomes necessary during the term of the contract.<br><br>Further development during the contract, if needed, will be formally asked for by BVO NL. |
| 1.23 | The incoming raw data files must be archived and retained in the secure data storage for the duration of the contract.                                                                                         |
| 1.24 | Tenderer agrees that the dataset that needs to be extracted from the raw files will be further defined and finalized at the start of the implementation of the project                                         |
| 1.25 | The QA Tool must be able to extract and archive the necessary data parameters.                                                                                                                                 |
| 1.26 | The QA Tool must provide a structured database for archiving the relevant data extracted from the raw data files.                                                                                              |
| 1.27 | The QA Tool contains a functionality to export and or print results presented in tables, figures and results from ad hoc queries.                                                                              |

#### Subject 1B: User roles

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| 1.28 | Each organisation will have a maximum of 5 users (3 laboratories and 1 BVO NL organization). This makes a total of 20 users.                                                                                                                   |
| 1.29 | The following user roles should be provided: <ul style="list-style-type: none"> <li>- Administrator (BVO-Only)</li> <li>- End-Users – View and print Reports (Labs + BVO)</li> </ul> Editor/developer roles will be fulfilled by the supplier. |
| 1.30 | The QA Tool enables complete access for the Reference officer to all data stored in the database.                                                                                                                                              |
| 1.31 | The QA Tool enables a laboratory to access its own data stored in the database.                                                                                                                                                                |
| 1.32 | The QA Tool enables a laboratory to see its own data being displayed in comparison to the results of the (blinded) other screening laboratories                                                                                                |

#### Subject 2: IT & security requirements

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| 2.1 | The required IT infrastructure for data storage and application server should be hosted by the supplier.                     |
| 2.2 | The QA Tool is offered as Software as a Service, which does not necessitate extra software to be downloaded before use.      |
| 2.3 | The QA Tool can be used browser independent via the internet.                                                                |
| 2.4 | The Database of the QA Tool must be secure and only accessible by authorized persons (based on authorization levels)         |
| 2.5 | The Storage must be managed by a separate organization department of the supplier (other than the QA tool application users) |
| 2.6 | Bevolkingsonderzoek Nederland decides which persons get authorisation to use the QA Tool.                                    |

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| 2.7  | All security frameworks from ISO27001 and/or NEN7510 are strictly complied with, as are the requirements as set out in the WABVPZ, including NEN7512 and NEN7513.              |
| 2.8  | Supplier must document and implement a backup and data-recovery strategy that will guarantee no data will be lost.                                                             |
| 2.9  | The Source database must be able to receive and store raw data-files from BD over the internet.                                                                                |
| 2.10 | Transfer of data by secure protocol; (i.e., Secure FTP, VPN, IPSec).                                                                                                           |
| 2.11 | The data must be stored in a secure and encrypted database (Storage, see Figure 1 Annex A) and must have different data accessibility profiles for different defined purposes. |
| 2.12 | The data for the quality assurance purposes should be extracted and anonymized to a separate datastore (The QA-Database, see Figure 1 Annex A)                                 |
| 2.13 | All data must be protected against cyberattacks amongst which is ransomware.                                                                                                   |
| 2.14 | According to Privacy rules, client related data must be traceable or removable from the QA Storage by a defined procedure upon request by BVO NL.                              |
| 2.15 | A specific selection of the Storage data must be accessible for export for a defined data science study on request and as defined by BVO NL.                                   |

#### Subject 3: Data protection requirements

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| 3.1 | Compliance with the Dutch Data Protection Act and successive legislation based on the GDPR is ensured by the Data Processing Agreement, Annex C.                                                                                                         |
| 3.2 | Compliance with the Dutch Data Protection Act and successive legislation based on the GDPR (this means amongst other things: no housing and hosting of the HPV QA monitoring application outside of European Economic Area, off shoring is not allowed). |
| 3.3 | The QA Tool uses documented access control and authorization levels.                                                                                                                                                                                     |
| 3.4 | Supplier always chooses the highest security level with regard to the exchange of personal data.                                                                                                                                                         |

#### Subject 4: Legal requirements

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| 4.1 | The agreement that will be the result of this tender (Annex B – Concept Agreement) is on the basis of ARBIT-2018 terms and conditions. Other terms and conditions are strictly excluded. |
| 4.2 | Escrow of the source and object code and access to those codes and documentation in case of bankruptcy or a takeover by another party.                                                   |
| 4.3 | Retransition and exit procedures without loss of data or threatening data security after the Contract was terminated.                                                                    |
| 4.4 | All data stored in- and analysed by the QA Tool remain the sole property of BVO NL.                                                                                                      |
| 4.5 | All data stored in- and analysed by the QA Tool can only be used by the provider of the QA Tool or any of its affiliates upon approval in writing by BVO NL.                             |

#### Subject 5: Commercial requirements

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| 5.1 | The prices for products, documentation and/or services are fixed for the duration of the Contract and can only be adjusted on the basis of the indexing method described in the Agreement |
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| 5.2 | The Supplier sends the invoice electronically to the following e-mail address of the Contracting Authority: <a href="mailto:crediteuren@bevolkingsonderzoeknederland.nl">crediteuren@bevolkingsonderzoeknederland.nl</a> |
| 5.3 | The Contracting Authority handles a payment of 30 days.                                                                                                                                                                  |

#### Subject 6: Support and maintenance requirements

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| 6.1  | The QA Tool offered must have a minimum availability on the basis of a full week (7 days x 24 hours) guarantee of 99.0% per month.                                                                                                                                                                                  |
| 6.2  | Supplier will provide management information at the end of every month from the start of the contract, which will gradually become once every 3 months (quarter of a year). The management information should at least contain the % availability of the QA Tool, the planned and unplanned downtime.               |
| 6.3  | Management, development and operation of the QA tool must take place in the Dutch or English language, with Dutch being preferred.<br><br>If BVO NL needs documentation regarding the operation of the QA tool in Dutch, the costs for translating are implied in the support and maintenance fee of the Tenderer.  |
| 6.4  | On a yearly basis supplier and BVO NL have at least two meetings in which operational issues can be addressed and management information can be discussed. The number of meetings may increase when the situation asks for it.                                                                                      |
| 6.5  | Planned downtime of the solution, including the availability of the QA Tool due to, for example, maintenance work, is coordinated in advance with the administrator of BVO-NL.                                                                                                                                      |
| 6.6  | Incidents (for example unplanned downtime) are reported to the administrator of BVO-NL by email. Immediate notification (but no later than within an hour) is required. In the event of unplanned downtime, there should be a notification visible on the system dashboard to be displayed to the users upon login. |
| 6.7  | Supplier keeps up – to – date documents regarding the QA Tool and maintenance of the QA Tool                                                                                                                                                                                                                        |
| 6.8  | Supplier provides a Service window during office hours (Monday through Friday from 08.00 - 18.00 CEST)                                                                                                                                                                                                              |
| 6.9  | The supplier resolves the problems within 1 working day (24 hrs) when the problem is blocking. Supplier consults BVO NL when the target of 1 working day cannot be met. Non-blocking problems may be resolved within 3 working days.                                                                                |
| 6.10 | Supplier provides technical support of the QA Tool                                                                                                                                                                                                                                                                  |
| 6.11 | The content of the Service Level Agreement (SLA) to be drawn up must at least meet the requirements of the tender.                                                                                                                                                                                                  |
| 6.12 | The Supplier conforms to the conclusion of a service level agreement, in which the Supplier takes an active role in the conclusion. The SLA must be definitive before the operational phase.                                                                                                                        |
| 6.13 | The Supplier conforms to the critical performance indicators set by the Client in order to monitor and secure the result components of the present order.                                                                                                                                                           |

#### Subject 7: Implementation requirements

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| 7.1 | Supplier provides a risk assessment for the use of the QA Tool (see award criterium AW2)                                                                                                                             |
| 7.2 | Supplier provides an implementation plan (see award criterium AW1)                                                                                                                                                   |
| 7.3 | A POC 4 weeks prior to the go live date is part of the implementation plan                                                                                                                                           |
| 7.3 | The QA Tool must be operational (ready for use) on the 1 <sup>st</sup> of June 2023.                                                                                                                                 |
| 7.4 | If the implementation is not completed on the 1 <sup>st</sup> of June 2023, BVO-NL is free (but not obliged) to use the Reserve Contract Agreement (Annex E) and to conclude an Agreement with the Waiting Tenderer. |

| Subject 8: Training |                                                                                                                                                     |
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| 8.1                 | Supplier organizes training for the use of the QA Tool to achieve that all users can use the QA Tool in accordance with their user roles and needs. |

| For approval                  |  |
|-------------------------------|--|
| Name Tenderer                 |  |
| Name legal representative     |  |
| Function legal representative |  |
| Date                          |  |
| Signature                     |  |